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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,693	01/26/2001	Steven V. Beer	19603/2501 (CRF D-2375A)	6816
7590 11/05/2003			EXAMINER	
Michael L. Goldman NIXON PEABODY LLP Clinton Square P.O. Box 31051 Rochester, NY 14603			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b> 09/770,693	<b>Applicant(s)</b> BEER ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 11-21 and 45-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 22-44 and 56-73 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on with the application is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The claims filed 1 August 2003 have been entered. Claims 1-10, 22-44 and 56-73 are pending.
2. This application contains claims 11-21 and 45-55 drawn to an invention nonelected with traverse in Paper No. 14. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The rejection of claims 1-2, 6-10, 22-28, 30-31, 34-36, 39-44, 56-62, 64-65, 67-70 and 72 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,174,717 in view of Wei et al (1998, US Patent 5,776,889) and further in view of Chappell et al (US Patent 5,981,843, filed May, 1995) is withdrawn in view of Applicant's arguments.
5. The rejection of claims 1-2, 6-7, 22-28, 30-31, 34-36, 39-41, 56-62, 64-65, 68-70 and 72 are rejected under 35 U.S.C. 102(e) as being anticipated by Chappell et al (US Patent 5,981,843, filed May, 1995) taken with the evidence of GenBank Accession No. U12639 is withdrawn in light of Applicant's amendments to the claims.

### ***Claim Rejections - 35 USC § 112***

6. Claims 1-10, 22-44 and 56-72 remain rejected and new claim 73 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for chimeric genes comprising SEQ ID NO:3 operably linked to the *gstI* promoter, with and without a signal sequence, cells transformed with the construct, and oomycete-resistant plants transformed with

the construct, does not reasonably provide enablement for constructs encoding any hypersensitive response elicitor operably linked to any promoter that is activated by an oomycete or to fragments of the *gstI* promoter and cells and plants transformed with those constructs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-10, 22-44 and 56-72. Applicant's arguments and the Declaration of Zhong-Min Wei, both filed 1 August 2003, have been fully considered but they are not persuasive.

Applicant summarizes the Wei Declaration; this will be addressed here by stating the arguments from the declaration. The Declaration urges that HR results from an incompatible interaction between pathogens and plants, and that HR elicitors are often homologous to one another. The Declaration urges that a gene encoding a HR elicitor from one source can be used to clone one from another source, and urges that HR elicitors are positioned within *hrp* gene clusters. The Declaration further urges that HR elicitors are secreted through the *hrp* dependent pathway whose regulation is controlled by environmental factors, and that they have a number of common characteristics, including being glycine rich, heat stable, hydrophilic, lacking an N-terminal signal sequence and having a common secondary structure. Finally, the Declaration urges that treatment of plants with HR elicitors resulted in disease resistance to a broad range of pathogens and enhanced plant growth, and the Declaration cites Gopalan, Bauer et al, Cui et al, Ahmad et al, Preston et al, Bonas I, Alfano et al, Swanson et al, Bognanove et al, Wei I, Bonas II, Fan et al, Wei II, Strobel et al, Qui et al, WO00/28055 and data within the Declaration itself as supporting evidence. Applicant urges that one of skill in the art would expect that what works

for HrpN would work for other hypersensitive response elicitors (response pg 13-18 and Declaration).

This is not found persuasive because the specification also does not teach *E. amylovora* hypersensitive response elicitor genes other than SEQ ID NO:3. Furthermore, the specification does not teach hypersensitive response elicitor genes not yet isolated.

Applicant urges that Li relates to the expression of HrmA, which is an effector protein, as taught by van Dijk et al; these proteins differ from the HR elicitors useful in the instant invention because the former function in plant cells, while the latter function within the apoplast, citing Alfano et al and Collmer et al (response pg 17-18).

This portion of the rejection is withdrawn in light of amendments to the claims.

Applicant urges that procedures for determining oocymete inducibility of a promoter is known in the art and thus need not be disclosed, for example in Keller et al, 1999. Applicant urges that Belbahri et al used the hsr203J promoter in a construct to induce oomycete resistance (response pg 18-19).

This is not found persuasive because this is not what the rejection was directed toward. Furthermore, Belbahri et al was published after the filing date of the instant applicant, and cannot be relied upon for enablement.

Applicant urges that one of ordinary skill in the art could identify promoter-effective regions of SEQ ID NO:9 via routine experimentation (response pg 19).

This is not found persuasive because given the unpredictability of promoter activity upon making deletions, as stated in Maiti et al, Chen et al, Benfrey et al, and Kim et al, cited in the prior office action, and given the lack of guidance in the specification, identifying fragments with

promoter activity from the myriad of fragments encompassed by the claims would require undue experimentation.

7. Claims 1-10, 22-44 and 56-72 remain rejected and new claim 73 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-10, 22-44 and 56-72. Applicant's arguments filed 1 August 2003 have been fully considered but they are not persuasive.

Applicant urges that four nucleic acids encoding HR elicitors from four bacterial species are taught in the specification, and the specification cites others (response pg 19-20).

This is not found persuasive because the specification does not describe the sequence of any nucleic acids encoding hypersensitive response proteins from *E. amylovora* other than SEQ ID NO:4 nor does it describe the features that distinguish *E. amylovora* hypersensitive response elicitor genes from other hypersensitive response elicitor genes. Furthermore, the specification does not describe hypersensitive response elicitor genes not yet isolated. Lastly, the specification does not describe promoter-effective fragments of the *gst1* promoter or more than one *gst1* promoter.

8. Claims 1-10, 22-44 and 56-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

The term “glycine rich” in claim 1 is a relative term which renders the claim indefinite. The term “glycine rich” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. How many or what proportion of glycine distinguishes a glycine rich protein from one that is not?

Claim 58 is indefinite in its recitation of “oomycete infection following expression of the first DNA molecule” in lines 8-9. Does oomycete infection result from expression of the DNA molecule? Or is something else intended?

***Claim Rejections - 35 USC § 102***

9. As Applicant’s arguments to these rejections are identical, they will be addressed together, after presentation of the rejections.
10. Claims 1-2, 6-7, 22-28, 30-31, 34-36, 39-41, 56-60, 62, 64-65, 68-70 and 72 remain rejected and new claim 73 is rejected under 35 U.S.C. 102(a) as being anticipated by Keller et al (1999, Plant Cell 11:223-235). The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-2, 6-7, 22-28, 30-31, 34-36, 39-41, 56-60, 62, 64-65, 68-70 and 72. Applicant’s arguments and the Declaration of Steven Beer, both filed 1 August 2003, have been fully considered but they are not persuasive.
11. Claims 1-2, 5-10, 22-31, 34-36, 41-44, 56-60, 62-65 and 70 remain rejected and new claim 73 is rejected under 35 U.S.C. 102(a) as being anticipated by Abdul-Kader et al (1999, Acta Hort. 489:247-250). The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-2, 5-10, 22-31, 34-36, 41-44, 56-60,

62-65 and 70. Applicant's arguments and the Declaration of Steven Beer, both filed 1 August 2003, have been fully considered but they are not persuasive.

Applicant urges that these rejections are improper in light of the Declaration of Dr. Steven Beer and Exhibit A. The Beer Declaration states that Exhibit A demonstrates that the claimed invention was reduced to practice prior to February 1999. Exhibit A and the Declaration describe constructs comprising the prp-1 promoter, the hrpN coding sequence and a 3' terminator, with and without a signal sequence; these constructs were transformed into Arabidopsis and the plants proved resistant to Peronospora (response pg 22 and Declaration).

This is not found persuasive for two reasons. First, a Declaration under 37 CFR 1.131 must be made by all of the inventors of the claimed subject matter, unless all of the named inventors are not the inventors of the claims under rejection (see MPEP 715.04). Second, the evidence submitted, Exhibit A, does not demonstrate that the instant inventors, S. Beer and D. Bauer conceived the claimed invention prior to the publication of the references. Exhibit A indicates that a third individual, Eric R. Garr, was an inventor of the claimed invention (see pg 1) and that Drs. Aldwinkle and Norelli were also involved; however, Eric Garr and Drs. Aldwinkle and Norelli are not inventors on the instant application. Thus, the rejections stand.

### ***Claim Rejections - 35 USC § 103***

12. Claims 1-10, 22-36, 41-44, 56-65 and 70-71 remain rejected and new claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Kader et al (1999, Acta Hort. 489:247-250) in view of Pfitzner et al (1987, Nuc. Acids Res. 15:4449-4465). The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to



claims 1-10, 22-36, 41-44, 56-65 and 70-71. Applicant's arguments filed 1 August 2003 have been fully considered but they are not persuasive.

Applicant urges that Abdul-Kader is not available as prior art and Pfitzber alone fails to teach or suggest each and every limitation of the claimed invention (response pg 22).

This is not found persuasive. Abdul-Kader is available for the reasons indicated above, and it, in combination with Pfitzner et al, does teach or suggest each and every limitation of the claimed invention

13. Claims 1-2, 5-10, 22-31, 34-38, 41-44, 56-67 and 70-71 remain rejected and new claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abdul-Kader et al in view of Scorza et al (1996, J. Amer. Hort. Sci. 121:616-619). The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-2, 5-10, 22-31, 34-38, 41-44, 56-67 and 70-71. Applicant's arguments filed 1 August 2003 have been fully considered but they are not persuasive.

Applicant urges that Abdul-Kader is not available as prior art and Scorza alone fails to teach or suggest each and every limitation of the claimed invention (response pg 22).

This is not found persuasive. Abdul-Kader is available for the reasons indicated above, and it, in combination with Scorza et al, does teach or suggest each and every limitation of the claimed invention

14. Claims 1-4, 6-7, 22-28, 30-33, 34-36, 39-41, 56-62, 64-65 and 68-72 remain rejected and new claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al (1999, Plant Cell 11:223-235) in view of Pfitzner et al (1987, Nuc. Acids Res. 15:4449-4465). The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-4, 6-7, 22-28, 30-33, 34-36, 39-41, 56-62, 64-65 and 68-72.

Applicant's arguments filed 1 August 2003 have been fully considered but they are not persuasive.

Applicant urges that Keller is not available as prior art and Pfitzner et al alone fails to teach or suggest each and every limitation of the claimed invention (response pg 23).

This is not found persuasive. Keller is available for the reasons indicated above, and it, in combination with Pfitzner et al, does teach or suggest each and every limitation of the claimed invention

15. Claims 1-2, 6-10, 22-28, 30-31, 34-44, 56-62 and 64-72 remain rejected and new claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over each of Chappell et al (US Patent 5,981,843, filed May, 1995) and Keller et al (1999, Plant Cell 11:223-235) in view of Zitter et al (US Patent 5,977,060, filed February 1997). The rejection is repeated for the reasons of record as set forth in the Office action mailed 30 January 2003, as applied to claims 1-2, 6-10, 22-28, 30-31, 34-44, 56-62 and 64-72. Applicant's arguments filed 1 August 2003 have been fully considered but they are not persuasive.

Applicant urges that Keller is not available as prior art (response pg 23).

This is not found persuasive. Keller is available for the reasons indicated above. Furthermore, the rejection was not of Chappell in view of Keller and further in view of Zitter, but was a rejection of each of Chappell and Keller in view of Zitter. Withdrawal of the rejection over Keller would not affect the rejection over Chappell in view of Zitter.

Applicant urges that Chappell, by specifically not reciting harpins in column 9, lines 54-57, excludes them from their definition of elicitors (response pg 21 and 23).

This is not found persuasive. Failure to recite harpins does not exclude them from a definition of elicitors, especially given that Chappell defines elicitors as proteins produced by plant pathogens that induce HR (column 1, line 66, to column 2, line 1).

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Anne R. Kubelik, Ph.D.  
October 20, 2003



AMY J. NELSON, PH.D.  
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